Performance and Implementation Evaluation of the Abbott BinaxNOW Rapid Antigen Test in a
High-throughput Drive-through Community Testing Site in Massachusetts

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Key words: COVID-19, SARS-CoV-2, diagnostic, antigen, point-of-care

Running title: BinaxNOW performance and implementation

Manuscript word count: 3714

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45 **Abstract**

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47
48 **Background:** Rapid diagnostic tests (RDTs) for SARS-CoV-2 antigens (Ag) that can be
49 performed at point-of-care (POC) can supplement molecular testing and help mitigate the
50 COVID-19 pandemic. Deployment of an Ag RDT requires an understanding of its operational
51 and performance characteristics under real-world conditions and in relevant subpopulations. We
52 evaluated the Abbott BinaxNOW™ COVID-19 Ag Card in a high-throughput, drive-through,
53 free community testing site in Massachusetts (MA) using anterior nasal (AN) swab RT-PCR for
54 clinical testing.

55
56 **Methods:** Individuals presenting for molecular testing in two of seven lanes were offered the
57 opportunity to also receive BinaxNOW testing. Dual AN swabs were collected from
58 symptomatic and asymptomatic children (≤ 18 years) and adults. BinaxNOW testing was
59 performed in a testing pod with temperature/humidity monitoring. One individual performed
60 testing and official result reporting for each test, but most tests had a second independent reading
61 to assess inter-operator agreement. Positive BinaxNOW results were scored as faint, medium, or
62 strong. Positive BinaxNOW results were reported to patients by phone and they were instructed
63 to isolate pending RT-PCR results. The paired RT-PCR result was the reference for sensitivity
64 and specificity calculations.

65
66 **Results:** Of 2482 participants, 1380 adults and 928 children had paired RT-PCR/BinaxNOW
67 results and complete symptom data. 974/1380 (71%) adults and 829/928 (89%) children were
68 asymptomatic. BinaxNOW had 96.5% (95% confidence interval [CI] 90.0- 99.3) sensitivity and
69 100% (98.6-100.0) specificity in adults within 7 days of symptoms, and 84.6% (65.1-95.6)
70 sensitivity and 100% (94.5-100.0) specificity in children within 7 days of symptoms. Sensitivity

71 and specificity in asymptomatic adults were 70.2% (56.6-81.6) and 99.6% (98.9-99.9),
72 respectively, and in asymptomatic children were 65.4% (55.6-74.4) and 99.0% (98.0-99.6),
73 respectively. By cycle threshold (Ct) value cutoff, sensitivity in all subgroups combined (n=292
74 RT-PCR-positive individuals) was 99.3% with Ct $\leq$ 25, 95.8% with $\leq$ 30, and 81.2% with $\leq$ 35.
75 Twelve false positive BinaxNOW results (out of 2308 tests) were observed; in all twelve, the test
76 bands were faint but otherwise normal, and were noted by both readers. One invalid BinaxNOW
77 result was identified. Inter-operator agreement (positive versus negative BinaxNOW result) was
78 100% (n = 2230/2230 double reads). Each operator was able to process 20 RDTs per hour. In a
79 separate set of 30 specimens (from individuals with symptoms $\leq$ 7 days) run at temperatures
80 below the manufacturer's recommended range (46-58.5°F), sensitivity was 66.7% and specificity
81 95.2%.

82
83 **Conclusions:** BinaxNOW had very high specificity in both adults and children and very high
84 sensitivity in newly symptomatic adults. Overall, 95.8% sensitivity was observed with Ct $\leq$ 30.
85 These data support public health recommendations for use of the BinaxNOW test in adults with
86 symptoms for $\leq$ 7 days without RT-PCR confirmation. Excellent inter-operator agreement
87 indicates that an individual can perform and read the BinaxNOW test alone. A skilled
88 laboratorian can perform and read 20 tests per hour. Careful attention to temperature is critical.

Introduction

Nucleic acid amplification tests (NAAT) for SARS-CoV-2, the etiologic agent of COVID-19, can be highly sensitive and are being performed at high volumes in centralized laboratories around the world (1, 2). Unfortunately, shortages of testing reagents and logistic barriers (e.g. sample transport) have impacted access to molecular testing and turnaround time for results. The need for decentralized testing options with short turnaround times has led to the development of rapid diagnostic tests (RDTs) for point-of-care (POC) use that detect SARS-CoV-2 nucleocapsid antigen (Ag) in as little as 15 minutes. As of December 26, 2020, there are 11 Ag RDTs with FDA Emergency Use Authorization (EUA) (3). Most of these tests can be performed by personnel without formal laboratory training in patient care settings that operate minimally under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver (COW).

Reported clinical sensitivities for Ag RDTs performed at POC in individuals suspected of COVID-19 vary widely, ranging from 74% to 97% compared with RT-PCR (4-12). Reports of false negative and false positive Ag RDT results (13) have raised concerns regarding their use, although a range of settings would benefit from RDT availability (e.g. K-12 schools, nursing homes, community testing centers, and home settings). Gaps in knowledge of how Ag RDTs perform in asymptomatic individuals and children remain.

In symptomatic adults, viral loads in nasopharyngeal (NP) samples peak within the first week of symptom onset, then decrease over a variable time frame; RNA levels in asymptomatically infected adults appear to follow similar kinetics (14, 15). Ag concentrations have been shown in one study to correlate tightly with Ct values in NP samples from adults and children (16). While NP sampling remains the reference method, anterior nasal (AN) sampling substantially increases

114 testing access and acceptability, and a recent head-to-head study suggested that Ag RDTs
115 performed on paired NP/AN samples yielded similar results (5).

116

117 The BinaxNOW COVID-19 Ag CARD (8) has FDA EUA for AN swab samples and can provide
118 visually-read results at POC in 15 minutes. The potential to use this test at large scale, combined
119 with the lack of data for test performance in asymptomatic adults and in children, motivated us to
120 perform an implementation and performance evaluation in a high-volume, high-prevalence
121 community testing site currently using AN swab RT-PCR for clinical testing.

122

123 **Methods:**

124

125 Study population

126 The study was performed between October 26-December 22, 2020 (all ages October 26-
127 November 12, 2020, and children only from December 11-22, 2020), at the Lawrence General
128 Hospital “Stop the Spread” drive-through testing site, which accommodates Massachusetts
129 residents from the surrounding area. No study-specific effort was made to recruit individuals to
130 present to the testing site. Two of seven drive-through lanes were utilized for the study. Verbal
131 consent for dual AN swabbing was obtained from adults and guardians of minors (with verbal
132 assent for ages 7-17). Participants were informed that they would be called for positive Ag RDT
133 results only and that positive results would require isolation while waiting for the RT-PCR result.
134 Presence or absence of symptoms (sore throat, cough, chills, body aches, shortness of breath,
135 fever, runny nose, congestion, nausea, vomiting, diarrhea, loss of taste or smell) was recorded for
136 each individual, including the date of symptom onset. Participants whose symptoms started on
137 the day of testing were classified as Day 0. The study was reviewed by the Massachusetts
138 Department of Public Health IRB and deemed not human subject research.

139

140 Swab collection procedure

141 Cars with consented patients were marked with a glass marker, notifying the specimen collector
142 to collect two AN swabs rather than one. Swab collection details are in Supplementary Methods;
143 in brief, collection involved swabbing both nostrils with each swab and operators alternated
144 which swab was collected first (for RT-PCR vs BinaxNOW). BinaxNOW swabs were captured
145 in an empty sterile tube and taken to the testing pod by a designated “runner.” Time of sample
146 collection was recorded.

147

148 Abbott BinaxNOW performance

149 Details of kit storage, quality control, and testing and results reporting procedures are in
150 Supplementary Methods.

151

152 RT-PCR assay

153 Dry AN swabs [SteriPack Sterile Polyester Spun Swab, 3” (Lakeland, Florida)] were collected
154 per site routine and transported at room temperature to the Broad Institute for testing using the
155 CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay under EUA
156 (17). Details are in Supplementary Methods.

157

158 Results reporting

159 All positive BinaxNOW results were reported to individuals the same day by Massachusetts
160 Department of Public Health (DPH) epidemiologists. Participants with positive BinaxNOW
161 results were informed that the result was presumptive and that they should maintain isolation for
162 a minimum of 10 days based upon the result, but that a confirmatory result would be obtained by
163 RT-PCR and reported in 1-2 days. If the RT-PCR result was negative, they could discontinue

164 isolation. RT-PCR results were provided to the patient by the Lawrence General Hospital's
165 portal or by walk up to a designated location at the Lawrence General Hospital. RT-PCR results
166 were reported to DPH through routine electronic laboratory reporting mechanisms and
167 individuals with positive results were referred to local boards of health or the Community
168 Tracing Collaborative for instruction on isolation and contact tracing.

169

170 Statistical analysis

171 Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) for
172 the BinaxNOW were calculated using the RT-PCR result as the reference. 95% CI were
173 calculated using the Clopper-Pearson method. Analyses utilized Microsoft Excel and GraphPad
174 Prism.

175

176 **Results:**

177

178 Four different lots of BinaxNOW kits were used for the study. Each operator was able to set up
179 a new test every 2-3 minutes, and two operators were able to manage testing of samples coming
180 from two drive-through lanes. All tests were initiated within 1 hour of collection, per
181 manufacturer instructions. Temperature and humidity in the testing pod (Supplementary
182 Methods) between 7:30AM-6:00PM ranged from 33.3-75.7°F and 27.8-81.0%, respectively, in
183 the shipping container and from 67.6-81.6°F and 20.8-69.0%, respectively, in the trailer. Tests
184 for the main study were not run until the temperature reached 59°F, per manufacturer's
185 recommendation. Data for tests performed out of the temperature range in the package insert
186 (<59°F) were analyzed separately (below).

187

188 Of 2482 participants [excluding samples tested at $<59^{\circ}\text{F}$ ($n=94$); inconclusive RT-PCR results
189 ($n=26$); and missing data ($n=54$)], 2308 had paired PCR/BinaxNOW results and complete
190 symptom data, including 829 asymptomatic children, 974 asymptomatic adults, 99 symptomatic
191 children, and 406 symptomatic adults. Symptomatic individuals were further classified as ≤ 7
192 days versus >7 days of symptoms. Clinical data for the study population are presented in Table 1
193 (demographics) and Supplementary Tables 1 and 2 (symptoms).

194
195 BinaxNOW performance in adults and children (≤ 18)

196 Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV)
197 calculations for BinaxNOW results versus RT-PCR results as the reference, for each clinical
198 subgroup, are presented in Table 2. Tables with data for each subgroup are presented in
199 Supplementary Table 3.
200 Sensitivity in adults with symptoms ≤ 7 days was 96.5%, similar to that in the BinaxNOW
201 package insert (97.1%) (8). Sensitivity in children with symptoms ≤ 7 days was 84.6%.
202 Specificity in both groups was 100%. Relative to symptomatic individuals, sensitivity in
203 asymptomatic adults and children was lower at 70.2% and 65.4%, respectively, while specificity
204 remained high (99.6%/99.0%, respectively). The anticipated NPV/PPVs with varying
205 prevalence, based on the observed sensitivity/specificity in each subgroup, are presented in
206 Supplementary Table 4.

207
208 Discordant analysis and analysis of Ct values

209 There were 12 false positive BinaxNOW results across all 2308 individuals tested; 4 were in
210 asymptomatic adults, 7 in asymptomatic children, and 1 in a symptomatic adult with >7 days of
211 symptoms. All twelve positives were scored as faint bands by both independent readers, and

212 there was nothing unusual noted about band morphology. 61/66 false negatives had dual read;
213 61/61 were scored as negative by both independent readers. There was no apparent correlation
214 between false positives/false negatives and lot or kit number in testing through Nov. 12th. In the
215 pediatric-only phase initiated Dec. 11th, all 6 false positive samples observed utilized one lot that
216 was not used in the first phase; there was no correlation between false negatives and lot number.
217
218 Distributions of Ct values for RT-PCR positive symptomatic (by days post symptom onset) and
219 asymptomatic children and adults are shown in Figure 1; false negative versus true positive
220 paired BinaxNOW results are indicated for all individuals. As expected, false negative
221 BinaxNOW results were paired with RT-PCR tests with higher Ct values. Ct distributions in the
222 four main clinical subgroups are shown in Figure 2. Median Ct values (IQR) for children and
223 adults symptomatic for ≤ 7 days were 24.2 (16.3-27.3) and 20.5 (17.2-26.5), respectively, and for
224 asymptomatic children and adults were 26.8 (20.5-32.8) and 26.9 (20.6-32.8), respectively.
225 Sensitivity was evaluated at three different Ct cutoffs: ≤ 25 , ≤ 30 , ≤ 35 (Supplementary Table 5).
226 Sensitivity in all subgroups combined (n=292 RT-PCR-positive individuals) was 99.3% with Ct
227 ≤ 25 , 95.8% with ≤ 30 , and 81.2% with ≤ 35 . Band strength (1= faint, n = 41; 2 = medium, n = 15;
228 3 = strong, n = 170) as interpreted by the primary reader for the 226 true positive BinaxNOW
229 tests correlated clearly with Ct value, with median Cts of 29.7 (27.6-32.7), 27.7 (25.5-29.1), and
230 19.5 (16.4-22.8), respectively, as shown in Supplementary Figure 1. All but one (65/66) false
231 negative BinaxNOW results had a paired RT-PCR cycle threshold value >25 , and 9 had Ct ≤ 30 ;
232 the median (IQR) cycle threshold value for these false negatives was 33.7 (32.1-34.8).
233 Distribution of the 66 false negative results among clinical subgroups is shown in the 2x2 tables
234 in Supplementary Table 3.
235

236 Operational findings

237 A small number of BinaxNOW tests were performed at temperatures below the manufacturer's
238 recommended temperature range due to difficulty maintaining temperature in the antigen testing
239 location and interest in exploring the effect of low temperature on test performance. These data
240 were analyzed separately from the main study. In 30 specimens from individuals (3 children and
241 27 adults) with symptoms ≤ 7 days run at low temperature (46-58.5°F), sensitivity was 66.7% and
242 specificity 95.2% (Supplementary Table 6), in comparison to sensitivity of 93.7% and specificity
243 of 100% in individuals with ≤ 7 days symptoms when testing was performed at $>59^\circ\text{F}$. Relative
244 humidity ranged from 45.7-66.4% during the two testing days with low temperatures ($\leq 59^\circ\text{F}$).
245 For false positive or false negative tests performed at $>59^\circ\text{F}$, the humidity range was 27.2-62.6%
246 and 22.6-61.5%, respectively, mirroring the overall humidity range and distribution.

247 Inter-operator agreement was excellent, with the two readers agreeing on the positive versus
248 negative result for all 2230 BinaxNOW tests that had dual reads. The two readers disagreed on
249 the strength of the positive band (faint vs medium vs strong) in 5 cases. Overall, readers noted
250 that detection of faint positive bands required very close observation. While we did observe
251 occasional inconsistent band intensity across the width of some test bands, we did not identify a
252 correlation between that finding and false positivity. One invalid BinaxNOW result was
253 identified during the study (a manufacturing issue whereby plastic covered the test strip,
254 preventing the buffer from making contact with the test strip).

255

256 **Discussion:**

257 The development of Ag RDTs has expanded the options for POC COVID-19 testing and raised
258 critical questions about how these tests could and should be used. Prominent examples of both
259 false negative and false positive results (13) on Ag RDTs have raised questions about how well
260

261 the tests perform in real world settings, even if performed carefully by trained operators. Major
262 gaps in performance data, including performance in asymptomatic adults and both symptomatic
263 and asymptomatic children, have generated uncertainty about how to optimally deploy Ag RDTs,
264 and emerging comparison studies reiterate that not all Ag RDTs perform equivalently (4, 18).
265 The FDA EUA for the BinaxNOW RDT was based upon 102 subjects, all adults, who had
266 symptomatic COVID-19 with symptom onset within 7 days prior to testing (8). In order to
267 understand how well the BinaxNOW RDT could perform in both symptomatic and
268 asymptomatic adults and children, we implemented the test at a high-volume community testing
269 site already experienced in collecting AN samples for RT-PCR, performing the test with careful
270 attention to sample collection, test performance, results documentation, and quality control. The
271 BinaxNOW was performed by trained laboratory personnel (Master's to PhD level
272 laboratorians). This study design allowed us to evaluate performance of the BinaxNOW in a real-
273 world but also best-case scenario, and to provide the first data on performance in a large
274 population of children.

275
276 We found that test specificity was very high in this study in all populations, while sensitivity was
277 variable. Sensitivity was very high in symptomatic adults within the first 7 days of illness, and
278 less so in symptomatic children. Sensitivity in asymptomatic adults and children was even
279 lower, corresponding with the broad viral load distribution observed in this population (likely
280 capturing early and late infections given unknown disease onset). For all groups, sensitivity was
281 highest in individuals with highest viral loads.

282
283 Our study yielded some important operational findings relevant to test implementation. Inter-
284 operator agreement on positive/negative results was 100%, confirming that only one person is

285 needed to read each test result. While one skilled operator was able to run 20 tests per hour, two
286 people were needed to run tests in high volume, and additional people were needed to transport
287 samples from the collection site to the testing site. We noticed a substantial impact of low
288 temperature (below the manufacturer's recommended range) on test accuracy, reinforcing that
289 temperature is a critical parameter for test performance; the instructions for use should be
290 followed closely and temperature should be monitored for every test performed. Gathering
291 additional data in summer months to confirm that test specificity remains high with elevated
292 environmental temperatures would be prudent.

293

294 Our data are consistent with, or show better performance than, those obtained in other field
295 studies of visually-read Ag RDTs. A recent European prospective study (4) evaluated visually-
296 read Ag RDT test performance at POC versus RT-PCR using nasopharyngeal/oropharyngeal
297 samples and found that the best-performing Ag RDT (Standard Q COVID-19 Ag, SD Biosensor)
298 was 76.6% sensitive and 99.3% specific, with 100% sensitivity in samples with Ct values <25
299 and 62.1% sensitivity in samples with Ct ≥ 25 (4). Another POC study of the SD Q test (NP
300 swab) versus RT-PCR (NP/OP swab) in symptomatic adults at a drive-through site in the
301 Netherlands (12) yielded Ag RDT sensitivity of 84.9% and specificity of 99.5%, with 95.8%
302 sensitivity in people within 7 days of symptoms and with Ct <30. A recent study of the Abbott
303 BinaxNOW versus AN swab RT-PCR as performed in adults on a public plaza in San Francisco
304 found that the test had 93.3% sensitivity in samples with Ct <30, and 99.9% specificity (9).
305 However, achieving this specificity required an off-label reading procedure in which the reader
306 was asked to disregard bands that did not extend across the full width of the strip. We did
307 observe occasional inconsistent band intensity across the width of some test bands, but did not
308 identify a correlation between that finding and false positivity. All twelve false positive tests in

309 our study had faint positive (and otherwise normal) bands scored by both independent readers.
310 The San Francisco study also used two readers for each test, with a tie breaker read if they
311 disagreed, but did not report data on inter-operator agreement. A study of the Abbott PanBio test
312 in symptomatic adults and children in Spain (11) compared POC Ag RDT (NP swab) to RT-PCR
313 (NP swab in 3.0 mL media) and found overall Ag RDT sensitivity of 79.6%, with specificity of
314 100%. Notably, sensitivity was higher in adults (82.6%) than children (62.5%), and sensitivity in
315 individuals with RT-PCR Ct <25 (viral load >5.9 log₁₀ copies/mL) was 100%; our own
316 observations are consistent with both findings. The authors speculated that the lower sensitivity
317 in symptomatic children versus adults might be due to more difficulty in pinpointing date of
318 symptom onset in children, which is also a possibility in our study. However, an alternative
319 explanation is that symptomatic children have a different distribution of viral loads than
320 symptomatic adults, with a higher proportion having lower viral loads (e.g. above Ct of 30)
321 within the first week of symptoms. This hypothesis is supported by distributions of Ct values
322 (and antigen concentrations) in NP swab samples from symptomatic adults versus children in a
323 recent study (16), but other studies of this question have yielded mixed results (19-21). Defining
324 viral load distributions and kinetics in symptomatic children remains an important area for
325 research.
326
327 Key considerations for use of Ag RDTs are whether they are able to reliably identify patients
328 with high loads of live virus that may be more at risk for transmitting disease, and whether
329 infected individuals missed by Ag RDTs might or might not be infectious to others. Several
330 reports have noted that virus could only rarely be cultured from patient samples with measured
331 viral loads below approximately 1×10⁵ RNA copies/mL (19, 22-24). Notably, Albert et al. found
332 that SARS-CoV-2 could not be cultured from specimens from 11 individuals with positive RT-

333 PCR/negative POC Abbott PanBio Ag RDT results, all with $<5.9 \log_{10}$ copies/mL (11), and Igloi
334 et al found that most culture-positive individuals were also positive by the SD Q assay (12).
335 Overlap between viral culture and Ag RDT percent positivity (versus RT-PCR) has also been
336 described for the BD Veritor System (25). However, virus has been recovered from samples with
337 RNA levels as low as 1.2×10^4 copies/mL (26), and from samples with a Ct value of 34-35 or
338 greater on a range of RT-PCR assays (27-29). Multiple evaluations of POC Ag RDT
339 performance have assessed performance at Ct value cutoffs of 25 and 30 (e.g. (4, 9)), which
340 guided our choice to assess sensitivity of the BinaxNOW at three different Ct cutoffs: 25, 30,
341 and 35. For the RT-PCR assay used in this study, Ct values of 25, 30, and 35 correspond to
342 approximately 5.4×10^5 , 1.7×10^4 , and 5.5×10^2 copies/mL, respectively (Niall Lennon, personal
343 communication; Supplementary Methods), and we found that patients with Ct values ≤ 30 were
344 reliably detected (95.8%) by the BinaxNOW, similar to results from Pilarowski et al (93.3%
345 sensitivity with Ct <30 , corresponding to 1.9×10^4 copies/mL (9)). A recent study of multiple
346 commercial Ag RDTs found that the analytical sensitivity range overlapped with viral load
347 ranges typically observed in the first week of symptoms, also considered to be the period of
348 highest infectiousness (18); consistent with this, we observed that the sensitivity of the
349 BinaxNOW in adults with ≤ 7 days of symptoms was 96.5%.
350
351 Our study had some limitations. We recognize that the comparator in our study was RT-PCR
352 performed on an AN swab, as opposed to an NP swab, which is still considered the reference
353 method by the FDA (30). While AN swabs have had lower sensitivity than NP swabs in some
354 studies, the sensitivity is highly dependent on the sampling technique and assay used (31). The
355 dry AN swab sampling method used in this study has been shown to have similar sensitivity to
356 paired NP swabs in transport media (17). We also note that a recent comparison study

357 demonstrated that Ag RDT performance with AN swabs was similar to Ag RDT performance
358 with NP swabs (5). We were not able to have all tests read by two independent readers, but did
359 so for the majority of tests. Finally, we recognize that our symptomatic pediatric cohort was
360 relatively small and thus the confidence interval relatively wide, exemplifying the challenges in
361 assessing COVID-19 diagnostics in children. There may be important differences in performance
362 characteristics of Ag tests or in viral dynamics corresponding to ages of children, but there were
363 insufficient symptomatic children with positive tests in the study to stratify by age group.

364

365 Current recommendations from the WHO (32) suggest that Ag RDTs be used in symptomatic
366 individuals within the first 5-7 days of symptoms, with repeat testing or RT-PCR confirmation of
367 negative Ag RDT results if possible. WHO recommendations include testing during suspected
368 outbreaks, monitoring trends in disease incidence, and screening for early detection/isolation
369 when widespread community transmission exists, but operationalizing testing under these
370 scenarios is complicated by the recommendations for confirmation by RT-PCR of both positive
371 (outbreak) and negative (symptomatic patient) results (32). Centers for Disease Control and
372 Prevention recommendations for use of antigen tests were recently updated and address use of
373 antigen tests (with/without NAAT confirmation) in various testing scenarios based on data to
374 date (33).

375

376 Our study data provides the following practical considerations for use of the BinaxNOW test in
377 different populations, taking into account current conditions in MA as reflected in prevalence at
378 this testing site (asymptomatic >5-10%; symptomatic >20%):

379

380 The test had particularly strong performance in adults with symptoms for ≤ 7 days, with very
381 high sensitivity (96.5%), specificity (100%), PPV (100%), and NPV (98.9%). In children with
382 symptoms ≤ 7 days, specificity (100%) and PPV (100%) were very high, but sensitivity was
383 lower than in adults (84.6% versus 96.5%) though still acceptable per the FDA's target of $\geq 80\%$
384 (34, 35)); NPV was 94.2%. Collection of additional data in symptomatic children will help
385 further support these conclusions.

386

387 In asymptomatic individuals, the BinaxNOW test had very high specificity in both children
388 (99.0%) and adults (99.6%); PPV was the same in children (90.9%) and adults (90.9%).
389 Sensitivity in children (65.4%) and adults (70.2%) was low. Thus, the test does not appear to be
390 optimal for ruling out SARS-CoV-2 infection in asymptomatic adults or children; use in serial
391 testing programs and for testing of contacts of known cases deserves independent study. FDA
392 does provide guidance for consideration of serial antigen testing if the sensitivity is lower, e.g.
393 70% (34, 35). It should be noted that in all groups, BinaxNOW sensitivity followed Ct value
394 distribution, with 95.8% sensitivity observed in all individuals with $Ct \leq 30$ (all 9 false negative
395 results in individuals with $Ct \leq 30$ were in children). Therefore, false negative BinaxNOW
396 results were largely confined to those perhaps least likely to transmit SARS-CoV-2.

397

398 Sensitivity (66.7%) was low in adults with symptoms for > 7 days, and there were too few
399 children with symptoms > 7 days to draw conclusions about performance. The test is not
400 currently recommended for use in individuals with symptoms > 7 days.

401

402 Quality Control (QC) testing should be performed per manufacturer's recommendations, with
403 weekly repeat of QC samples if the kit has not been fully used. It would be prudent to reevaluate

404 test specificity in warm conditions; careful attention to temperature is critical. A skilled
405 laboratorian can perform and read 20 tests per hour. Excellent inter-operator agreement indicates
406 that an individual can perform and read the BinaxNOW test alone.

407
408 **Funding**

409 This work was funded by the MA Department of Public Health. The community testing site was
410 funded by the Centers for Disease Control and Prevention Building and Enhancing
411 Epidemiology, Laboratory and Health Information Systems Capacity in Massachusetts –
412 Enhancing Detection COVID Supplement (Grant # 6 NU50CK000518-01-08). BinaxNOW kits
413 were supplied as part of the federal allocation to state health departments.

414

415 **Conflict of Interest**

416 None of the authors have conflicts of interest to declare.

417

418 **Acknowledgments**

419 We thank Kerin Milesky (Director, Office of Emergency Preparedness, Massachusetts
420 Department of Public Health), Samantha Phillips (Director, Massachusetts Emergency
421 Management Agency), and members of the Massachusetts State Fire Services (Bill Pappas, Mike
422 Burnell, Emit Magdeleno, Greg Jackson, Ed Loader) for assistance with logistical and support
423 assistance at the Lawrence General Hospital Stop the Spread site. We acknowledge the
424 assistance of the members of the Epidemiology Division of the Bureau of Infectious Disease and
425 Laboratory Sciences of the Massachusetts Department of Public Health.

426 This publication was supported by Cooperative Agreement Number 1U60OE000103, funded by
427 Centers for Disease Control and Prevention through the Association of Public Health
428 Laboratories. The findings and conclusions in this report are those of the authors and do not

429 necessarily represent the official position of the Centers for Disease Control and Prevention
430 (CDC) nor the official views of the Association of Public Health Laboratories.
431

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Table 1**Clinical characteristics of adult and pediatric patients contributing paired samples**

	Adults, symptomatic (n=407)	Adults, asymptomatic (n=974)	Children, symptomatic (n=99)	Children, asymptomatic (n=829)
Age in years, n (%)				
<7	n/a	n/a	17	244
7-13	n/a	n/a	42	339
14-18	n/a	n/a	40	246
19-29	120	212	n/a	n/a
30-49	189	392	n/a	n/a
50-69	89	312	n/a	n/a
70 and older	8	58	n/a	n/a
Sex, % female	58.9	56.4	61.6	52.0
Days of symptoms prior to COVID test, median (IQR)	3 (2,5) ^a	n/a	2 (1,4) ^b	n/a

^aRange 0-55 days^bRange 0-60 days

570

571 **Table 2**

572

573 **Performance of the Abbott BinaxNOW versus RT-PCR (reference method) for detection of**
574 **SARS-CoV-2 in anterior nasal swab samples from adult and pediatric (≤ 18) patients**
575

Age	Group	N	Prevalence	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
All	Sx + ASx	2308	12.7%	77.4% (72.2 - 82.1)	99.4% (99.0 - 99.7)	95.0% (91.5 - 97.1)	96.8% (96.1 - 97.4)
Pediatric	Sx + ASx	928	14.5%	69.6% (61.1 - 77.2)	99.0% (98.2 - 99.6)	92.1% (84.7 - 96.1)	95.7% (94.5 - 96.6)
Adult	Sx + ASx	1380	11.4%	84.1% (77.4 - 89.4)	99.6% (99.1 - 99.9)	96.4% (91.7 - 98.5)	98.0% (97.1 - 98.6)
Pediatric	ASx	829	12.9%	65.4% (55.6 - 74.4)	99.0% (98.0 - 99.6)	90.9% (82.5 - 95.5)	95.1% (93.7 - 96.2)
Adult	ASx	974	5.9%	70.2% (56.6 - 81.6)	99.6% (98.9 - 99.9)	90.9% (78.8 - 96.4)	98.1% (97.3 - 98.8)
Pediatric	Sx ≤ 7 D	91	28.6%	84.6% (65.1 - 95.6)	100.0% (94.5 - 100.0)	100.0%	94.2% (86.8 - 97.6)
Adult	Sx ≤ 7 D	355	23.9%	96.5% (90.0 - 99.3)	100.0% (98.6 - 100.0)	100.0%	98.9% (96.7 - 99.6)
Pediatric	Sx > 7 D	8	25%	N/A	N/A	N/A	N/A
Adult	Sx > 7 D	51	29.4%	66.7% (38.4 - 88.2)	97.2% (85.5 - 99.9)	90.9% (58.3 - 98.6)	88.2% (77.4 - 95.6)

576 Sx, symptomatic; ASx, asymptomatic; D, days; N/A, not applicable

577

Figure 1

Distribution of Cycle Threshold (Ct) Values in RT-PCR-positive Children and Adults by Days Post Symptom Onset

Ct values for each RT-PCR-positive individual are shown; red circles indicate false negative BinaxNOW results and black circles, true positive BinaxNOW results. Participants whose symptoms started on the day of testing are indicated as Day 0. ASx, asymptomatic.

591 **Figure 2**
592
593 **Distribution of Ct Values in RT-PCR-positive Individuals**
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598 Cycle threshold (Ct) values for RT-PCR positive individuals in each of four clinical subgroups
599 are shown; horizontal bars represent median and IQR. Sx, symptomatic; ASx, asymptomatic; D,
600 Days. Median Ct values (IQR) in Sx ≤7D: Children, 24.2 (16.3-27.3) and Adults, 20.5 (17.2-
601 26.5) and in ASx: Children, 26.8 (20.5-32.8) and Adults, 26.9 (20.6-32.8).
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Supplementary Materials

Supplementary Methods

Anterior Nasal Swab Collection procedure

The following swab collection procedure was utilized: after the participant blew their nose, the collector inserted swab #1 into the individual's right nostril and rotated the swab 5 times in a circular motion around the inside wall of the nostril for a duration of 10-15 seconds, followed by a repeat of the process in the left nostril. The swab was placed into a sterile plastic tube. Immediately thereafter, swab #2 was inserted into the individual's left nostril (always opposite from the initial swab) and the process repeated (left nostril followed by right nostril). To minimize sampling bias, the study site personnel alternated which test-specific nasal swab sample was collected first (BinaxNOW or RT-PCR).

Kit Storage

Abbott BinaxNOW kits were stored in a temperature-controlled office (70-72°F) and transferred to the testing site as needed.

Testing Site

Testing was performed in a "testing pod," initially a shipping container. The pod was initially open on one side to the outdoors, but difficulty in maintaining adequate temperature in the pod required moving testing to a fully enclosed room (mobile trailer). The testing site contained three 6' tables. Two tables were designated as "dirty" for testing purposes and one "clean" for data entry. Absorbent underpads with plastic backing (Attends ASB-2336, Greenville, NC) were placed on testing tables along with hand sanitizer, gloves, testing kits, pens, sticky notes, a

continuous temperature and humidity data logger (HOBO UX100-011A, Bourne, MA), a digital clock, and a bin for specimens to be tested. The clean table included hand sanitizer, gloves, pens, a time stamp machine, and a laptop computer for data entry. Underpads were removed daily, surfaces were disinfected with germicidal disposable wipes (PDI, Woodcliff Lake, NJ), and new underpads placed. Operators performing testing were wearing disposable gowns, N95 respirators, face shields and gloves.

Quality Control

Lot numbers were recorded for Abbott BinaxNOW kits (boxes of 40 tests), test cards, manufacturer-provided swabs [unflocked foam tipped; Puritan #25-1506 (Guilford, ME)], positive controls, and extraction reagent. Manufacture and expiration dates were also recorded. Each study subject tested was recorded for every kit of BinaxNow tests used. Positive and negative controls were run for every kit when first opened. If an opened kit was not used in full over the course of one day, a negative control was run for the kit the following day when testing resumed.

BinaxNOW Testing

At the collection site, anterior nasal swab specimens were collected using the manufacturer-provided swab (above) into a labeled 15ml conical tube and placed into a specimen collection bag with a BinaxNow intake form (which was labeled and time/date stamped at the time of collection) and extra labels. Specimens were then shuttled to the testing pod by a designated individual (“runner”), either on foot (shipping container) or by car (mobile trailer). All tests were initiated within an hour of specimen collection time. For each specimen, testing staff added 6 drops of extraction reagent to the BinaxNOW card (making sure to remain perpendicular and

avoid touching the tip of the reagent bottle to the card), inserted the swab specimen and rotated three times, closed the testing card, and affixed a patient label to the outside of the BinaxNOW card. The time the card was closed was recorded on the BinaxNOW intake form as the test start time. The test start time and time the card was to be read (16 minutes after closing the card) were also recorded on a sticky note and adhered to the outside of the BinaxNOW card. At the time of result reading, the tester silently recorded their result, initials, and time on the Binax intake form as the official result. The tester then passed the card to a second reader, who read the card result aloud (so that the tester could record results on the back of the intake form) and took a photo of the card. There was no attempt to resolve any discordance between the two readers; the first read of each card was the official result used for database and clinical reporting. If the result was determined to be positive by either reader, the reader categorized the positive line as “faint”, “medium”, or “strong” depending on the strength of the positive sample line compared to the control line of each card. Completed BinaxNOW cards were discarded in biohazard waste.

PCR assay details

Dry swabs [SteriPack Sterile Polyester Spun Swab, 3” (Lakeland, Florida)] transported in a sterile tube (Becton Dickinson, # BD 366408) at room temperature were resuspended in 1000 uL of Swab Preservation Buffer (Norgen Biotek, Inc) and allowed to elute for 15 minutes. Extraction and RT-PCR methods followed the EUA protocol for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (<https://www.fda.gov/media/139858/download>); the target is the N2 gene with a cycle threshold cut off value of 40. A standard curve was prepared with FDA reference panel material [heat inactivated virus from BEI Resources (www.beiresources.org)] using serial dilutions (in

triplicate) made in negative clinical matrix then spiked onto dry swabs, allowed to dry, and subsequently taken all the way through the process.

Supplementary Table 1

Abbott BinaxNow results, RT-PCR Ct values, and symptoms in RT-PCR-positive adults

Age	Sex	PCR Result	Ct (N2)	Ct (RP)	Binax Result	COVID-19 symptoms?	Sore throat?	Cough?	Chills?	Body Aches?	Short of breath?	Fever?	Runny Nose?	Congestion?	Nausea?	Vomiting?	Diarrhea?	Loss of Taste or Smell?	# Days Since Symptom Onset
21	F	POS	34.26	19.58	NEG	ASx													n/a
23	M	POS	35.48	25.16	NEG	ASx													n/a
26	M	POS	35.43	25.88	NEG	ASx													n/a
27	M	POS	35.17	24.26	NEG	ASx													n/a
28	F	POS	34.66	26.29	NEG	ASx													n/a
30	M	POS	35.19	20.77	NEG	ASx													n/a
33	M	POS	32.76	24.52	NEG	ASx													n/a
34	M	POS	32.36	22.42	NEG	ASx													n/a
38	F	POS	31.22	21.78	NEG	ASx													n/a
39	M	POS	37.03	28.61	NEG	ASx													n/a
48	M	POS	35.29	27.46	NEG	ASx													n/a
50	F	POS	34.87	21.31	NEG	ASx													n/a
50	F	POS	34.73	24.63	NEG	ASx													n/a
56	F	POS	32.3	26.75	NEG	ASx													n/a
60	F	POS	31.6	26.5	NEG	ASx													n/a
71	M	POS	33.2	19.62	NEG	ASx													n/a
81	M	POS	34.56	24.54	NEG	ASx													n/a
21	M	POS	14.62	23.23	POS	ASx													n/a
22	F	POS	32.89	30.74	POS	ASx													n/a
22	M	POS	27.74	22.13	POS	ASx													n/a
23	F	POS	18.75	25.23	POS	ASx													n/a
23	F	POS	26.75	24.18	POS	ASx													n/a
24	M	POS	29.67	21.5	POS	ASx													n/a
25	M	POS	14.1	19.83	POS	ASx													n/a
27	F	POS	20.69	27.21	POS	ASx													n/a
28	M	POS	23.63	27.99	POS	ASx													n/a
29	F	POS	22.21	24.08	POS	ASx													n/a
31	F	POS	17.55	27.16	POS	ASx													n/a
31	M	POS	14.57	22.16	POS	ASx													n/a
32	M	POS	28.17	24.67	POS	ASx													n/a
34	F	POS	22.47	27.53	POS	ASx													n/a
35	F	POS	17.39	23.93	POS	ASx													n/a
38	M	POS	26.95	24.65	POS	ASx													n/a
39	F	POS	20.82	29.82	POS	ASx													n/a
42	F	POS	13.65	22.24	POS	ASx													n/a
42	F	POS	28.4	25.58	POS	ASx													n/a
46	M	POS	12.82	20.87	POS	ASx													n/a
48	F	POS	16.4	24.47	POS	ASx													n/a
49	F	POS	22.3	23.42	POS	ASx													n/a
50	M	POS	16.35	24.14	POS	ASx													n/a
51	M	POS	26.91	23.37	POS	ASx													n/a
51	M	POS	17.16	23.86	POS	ASx													n/a
53	F	POS	25.78	23.3	POS	ASx													n/a
53	F	POS	21.4	23.19	POS	ASx													n/a
54	F	POS	28.3	21.6	POS	ASx													n/a
57	F	POS	21.66	24.84	POS	ASx													n/a
60	M	POS	28.65	26.5	POS	ASx													n/a
61	F	POS	15.64	26.47	POS	ASx													n/a
61	M	POS	24.4	27.67	POS	ASx													n/a
61	M	POS	21.61	27.39	POS	ASx													n/a
63	F	POS	25.94	28.19	POS	ASx													n/a
64	M	POS	32.01	23.85	POS	ASx													n/a
65	M	POS	26.09	21.92	POS	ASx													n/a
67	F	POS	15.4	24.6	POS	ASx													n/a
71	F	POS	28.45	22.76	POS	ASx													n/a
71	M	POS	32.83	25.58	POS	ASx													n/a
79	F	POS	20.55	24.67	POS	ASx													n/a
29	M	POS	32.54	24.93	NEG	Sk		Y	Y			Y	Y	Y					2
32	F	POS	31.56	20.47	NEG	Sk		Y	Y	Y			Y	Y					2
63	M	POS	33.77	24.45	NEG	Sk		Y											1
19	M	POS	26.23	23.73	POS	Sk	Y		Y										3
20	F	POS	20.47	22.8	POS	Sk	Y	Y	Y	Y			Y	Y					3
20	M	POS	27.87	24.95	POS	Sk	Y	Y					Y	Y					4
20	M	POS	14.55	22.4	POS	Sk							Y						0
21	F	POS	17.94	23.13	POS	Sk		Y	Y		Y		Y	Y					2
21	M	POS	16.28	23.96	POS	Sk		Y	Y	Y		Y	Y	Y					2
22	F	POS	20.59	21.94	POS	Sk		Y			Y		Y	Y			Y	Y	3
23	F	POS	20.16	27.91	POS	Sk				Y			Y	Y		Y		Y	3
23	F	POS	27.72	28.5	POS	Sk	Y	Y	Y	Y		Y			Y		Y		2
24	M	POS	20.41	28.39	POS	Sk	Y		Y	Y		Y	Y	Y				Y	1
25	M	POS	29.26	22.36	POS	Sk	Y	Y		Y			Y	Y				Y	4
25	F	POS	20.81	25.63	POS	Sk		Y				Y	Y					Y	2
25	F	POS	19.47	21.79	POS	Sk	Y	Y		Y			Y	Y				Y	3
25	M	POS	26.26	24.39	POS	Sk	Y	Y	Y	Y	Y	Y	Y						3
26	M	POS	15.62	24.26	POS	Sk	Y						Y	Y					1
26	F	POS	19.19	22.21	POS	Sk	Y	Y											2
27	F	POS	17.79	25.23	POS	Sk	Y	Y	Y	Y			Y	Y					2

27	M	POS	15.95	24.3	POS	5x	Y			Y		Y	Y	Y	Y			2
27	F	POS	18.81	23.78	POS	5x		Y	Y	Y		Y	Y					2
28	M	POS	25.41	24.61	POS	5x				Y			Y		Y	Y		4
29	F	POS	16.5	21.78	POS	5x											Y	0
29	M	POS	18.2	23.42	POS	5x							Y					1
30	M	POS	27.23	29.61	POS	5x		Y	Y	Y	Y		Y	Y	Y			2
31	F	POS	25.48	24.96	POS	5x	Y	Y	Y	Y	Y	Y	Y					3
31	F	POS	18.33	25.67	POS	5x		Y	Y					Y				1
31	F	POS	21.89	26.98	POS	5x				Y	Y		Y	Y	Y		Y	4
31	F	POS	15.21	23.27	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	4
31	M	POS	16.17	21.38	POS	5x		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	0
32	F	POS	29.47	26.43	POS	5x				Y		Y	Y	Y		Y		6
32	F	POS	13.77	24.14	POS	5x												1
32	M	POS	26.76	24.76	POS	5x		Y		Y		Y	Y				Y	3
33	M	POS	24.36	21.6	POS	5x			Y				Y		Y		Y	3
33	F	POS	14.32	22.84	POS	5x		Y	Y		Y			Y				1
33	F	POS	17.12	21.83	POS	5x		Y		Y			Y	Y				1
34	M	POS	27.63	26.65	POS	5x				Y		Y	Y				Y	2
34	F	POS	30.52	23.25	POS	5x	Y		Y				Y	Y		Y	Y	5
34	M	POS	18.75	22.42	POS	5x	Y	Y	Y	Y	Y							3
35	F	POS	22.88	28.59	POS	5x		Y	Y	Y	Y					Y		1
35	F	POS	16.4	22.27	POS	5x	Y			Y								1
35	F	POS	20.19	22.43	POS	5x	Y	Y	Y	Y			Y	Y		Y	Y	3
35	M	POS	25.06	26.91	POS	5x	Y	Y	Y								Y	2
35	M	POS	27.25	22.99	POS	5x	Y	Y	Y				Y	Y	Y			3
36	F	POS	22.81	27.54	POS	5x		Y		Y		Y	Y					1
37	F	POS	19.5	26.99	POS	5x	Y	Y	Y	Y		Y	Y	Y			Y	2
37	M	POS	22.18	21.61	POS	5x	Y	Y	Y	Y								2
38	M	POS	18.33	27.29	POS	5x	Y	Y	Y		Y	Y	Y	Y				6
38	F	POS	31.41	22.64	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y	Y			1
38	F	POS	28.04	22.86	POS	5x					Y						Y	2
39	M	POS	29.14	29.32	POS	5x		Y	Y	Y	Y	Y	Y	Y	Y		Y	6
39	F	POS	15.41	22.8	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y			Y	1
40	M	POS	20.77	24.58	POS	5x		Y	Y	Y	Y		Y				Y	1
40	F	POS	21.26	25.98	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y				5
40	M	POS	23.03	20.72	POS	5x	Y						Y				Y	2
41	M	POS	17.23	24.19	POS	5x					Y							3
41	M	POS	19.24	21.43	POS	5x	Y	Y		Y	Y	Y						2
42	M	POS	23.2	24.16	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y			Y	2
44	F	POS	17.67	25.61	POS	5x		Y	Y	Y								1
44	F	POS	15.2	22.19	POS	5x	Y	Y		Y	Y							3
45	M	POS	18.7	23.76	POS	5x		Y	Y	Y								3
45	F	POS	21.15	24.76	POS	5x	Y	Y	Y	Y		Y	Y	Y	Y			3
46	F	POS	15.2	27.54	POS	5x	Y	Y		Y								2
47	F	POS	32.6	27.59	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	6
47	M	POS	26.77	23.56	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y	Y			5
48	F	POS	34.58	24.96	POS	5x	Y	Y		Y	Y	Y	Y	Y			Y	3
48	M	POS	21.82	24.66	POS	5x			Y	Y	Y	Y	Y	Y				2
49	M	POS	30.73	21.95	POS	5x		Y										5
49	M	POS	19.16	21.67	POS	5x						Y						0
50	F	POS	20.45	21.07	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y	Y			0
51	F	POS	16.57	26.99	POS	5x		Y	Y	Y	Y		Y	Y		Y	Y	1
51	M	POS	15.46	21.47	POS	5x	Y	Y	Y	Y								1
54	M	POS	24.18	24.5	POS	5x		Y	Y		Y		Y					1
54	F	POS	16.92	22.82	POS	5x	Y	Y	Y			Y					Y	3
54	M	POS	11.78	18.96	POS	5x				Y	Y	Y	Y				Y	1
57	M	POS	18.69	28.26	POS	5x			Y	Y	Y	Y	Y	Y	Y			1
57	F	POS	21.8	24.73	POS	5x	Y	Y		Y		Y	Y					1
60	F	POS	16.18	25.74	POS	5x	Y					Y						1
61	M	POS	18.82	25.48	POS	5x		Y	Y			Y	Y	Y				2
65	F	POS	14.61	23.24	POS	5x			Y	Y	Y	Y	Y	Y	Y			3
66	M	POS	15.35	18.78	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		3
67	M	POS	33.69	25.16	POS	5x					Y	Y	Y	Y				2
70	M	POS	26.78	26.3	POS	5x	Y	Y	Y	Y	Y	Y	Y	Y				0
70	M	POS	22	25.3	POS	5x		Y										2
32	M	POS	34.2	26.37	NEG	5x7+				Y	Y		Y			Y	Y	7+
32	F	POS	34.05	23.27	NEG	5x7+												7+
33	F	POS	33.79	25.58	NEG	5x7+		Y		Y	Y		Y	Y			Y	7+
43	M	POS	34.56	25.89	NEG	5x7+		Y	Y	Y		Y	Y					7+
67	F	POS	30.4	25.95	NEG	5x7+								Y	Y			7+
19	F	POS	22.78	22.71	POS	5x7+							Y	Y				7+
20	M	POS	29.39	22.48	POS	5x7+		Y		Y	Y		Y	Y				7+
25	F	POS	29.8	24.6	POS	5x7+		Y	Y									7+
30	F	POS	17.71	27.39	POS	5x7+	Y	Y					Y					7+
30	M	POS	14.71	23.66	POS	5x7+	Y	Y	Y									7+
34	M	POS	25.94	26.03	POS	5x7+	Y	Y	Y		Y		Y				Y	7+
43	F	POS	27.12	19.54	POS	5x7+												7+
50	F	POS	34.56	24.45	POS	5x7+						Y	Y				Y	7+
53	M	POS	17.8	23.87	POS	5x7+		Y	Y		Y				Y			7+
68	M	POS	20.24	23.53	POS	5x7+		Y									Y	7+

F, female; M, male; POS, positive; Ct, cycle threshold; N2, SARS-CoV-2 target; RP, host control target; ASx, asymptomatic; Sx, symptomatic; n/a, not applicable

Supplementary Table 2

Abbott BinaxNow results, RT-PCR Ct values, and symptoms in RT-PCR-positive children

Age	Sex	PCR Result	Ct (N2)	Ct (RP)	Binax Result	COVID-19 symptoms?	Sore throat?	Cough?	Chills?	Body Aches?	Short of Breath?	Fever?	Runny Nose?	Congestion?	Nausea?	Vomiting?	Diarrhea?	Loss of Taste or Smell?	# Days Since Symptom Onset
0	F	POS	33.59	21.55	NEG	Asx													n/a
0	M	POS	29.89	20.61	NEG	Asx													n/a
1	M	POS	34.26	21.97	NEG	Asx													n/a
2	M	POS	37.1	26.4	NEG	Asx													n/a
3	F	POS	31.7	21.76	NEG	Asx													n/a
3	F	POS	26.7	19.84	NEG	Asx													n/a
3	F	POS	36.51	24.03	NEG	Asx													n/a
3	M	POS	28.93	21.76	NEG	Asx													n/a
3	M	POS	32.44	24.73	NEG	Asx													n/a
3	F	POS	32.31	22.46	NEG	Asx													n/a
5	M	POS	32.87	26.98	NEG	Asx													n/a
6	F	POS	26.82	22.58	NEG	Asx													n/a
7	F	POS	33.01	20.2	NEG	Asx													n/a
7	F	POS	30.99	21.65	NEG	Asx													n/a
7	F	POS	33.72	23.35	NEG	Asx													n/a
7	M	POS	36.31	24.21	NEG	Asx													n/a
8	M	POS	34.62	22.23	NEG	Asx													n/a
9	M	POS	34.34	22.58	NEG	Asx													n/a
9	M	POS	27.42	21.64	NEG	Asx													n/a
10	F	POS	32.47	22.45	NEG	Asx													n/a
10	M	POS	34.07	25.45	NEG	Asx													n/a
12	F	POS	27.45	24.01	NEG	Asx													n/a
12	M	POS	39.84	24.35	NEG	Asx													n/a
12	M	POS	23.43	20.22	NEG	Asx													n/a
12	F	POS	32.83	24.29	NEG	Asx													n/a
13	F	POS	26.89	21.82	NEG	Asx													n/a
14	F	POS	32.78	23.33	NEG	Asx													n/a
15	F	POS	36.84	20.19	NEG	Asx													n/a
15	F	POS	33.39	22.53	NEG	Asx													n/a
16	M	POS	36.5	19.31	NEG	Asx													n/a
16	F	POS	33.08	22.33	NEG	Asx													n/a
16	F	POS	33.5	19.98	NEG	Asx													n/a
16	F	POS	35.4	22.32	NEG	Asx													n/a
17	F	POS	34.88	24.47	NEG	Asx													n/a
17	M	POS	34.47	25.58	NEG	Asx													n/a
18	F	POS	32.22	21.37	NEG	Asx													n/a
18	F	POS	33.9	26.17	NEG	Asx													n/a
0	M	POS	13.48	23.3	POS	Asx													n/a
0	F	POS	17.72	27.64	POS	Asx													n/a
0	F	POS	32.61	20.25	POS	Asx													n/a
1	F	POS	27.34	21.61	POS	Asx													n/a
1	M	POS	14.35	20.71	POS	Asx													n/a
1	M	POS	19.05	26.8	POS	Asx													n/a
2	F	POS	29.77	25.68	POS	Asx													n/a
2	F	POS	25.61	19.76	POS	Asx													n/a
2	M	POS	16.75	20.83	POS	Asx													n/a
2	F	POS	21.51	20.22	POS	Asx													n/a
2	F	POS	22.88	20.41	POS	Asx													n/a
3	F	POS	23.96	22.89	POS	Asx													n/a
3	F	POS	20.94	20.45	POS	Asx													n/a
3	M	POS	25.56	20.35	POS	Asx													n/a
4	M	POS	21.68	19	POS	Asx													n/a
5	M	POS	27.84	18.48	POS	Asx													n/a
6	F	POS	29.61	19.83	POS	Asx													n/a
6	M	POS	17.63	21.84	POS	Asx													n/a
6	M	POS	13.11	20.96	POS	Asx													n/a
6	M	POS	21.53	24.64	POS	Asx													n/a
7	M	POS	27.57	22.55	POS	Asx													n/a
7	F	POS	21.51	22.87	POS	Asx													n/a
7	M	POS	14.5	23.54	POS	Asx													n/a
7	M	POS	22.1	28.85	POS	Asx													n/a
7	F	POS	27.82	23.9	POS	Asx													n/a
7	F	POS	29.83	20.78	POS	Asx													n/a
7	F	POS	18.13	24.45	POS	Asx													n/a
8	F	POS	18.38	28.23	POS	Asx													n/a
8	F	POS	15.28	22.14	POS	Asx													n/a
8	F	POS	14.66	20.35	POS	Asx													n/a

8	F	POS	32.73	21.97	POS	ASx												n/a
8	M	POS	22.99	22.95	POS	ASx												n/a
8	F	POS	22.4	24.28	POS	ASx												n/a
9	F	POS	19.96	22.67	POS	ASx												n/a
9	F	POS	15.45	21.72	POS	ASx												n/a
9	F	POS	23.99	19.95	POS	ASx												n/a
9	M	POS	34.59	22.05	POS	ASx												n/a
9	M	POS	20.54	23.4	POS	ASx												n/a
9	F	POS	14.54	21.84	POS	ASx												n/a
10	M	POS	35.88	25.08	POS	ASx												n/a
10	F	POS	26.85	24.5	POS	ASx												n/a
11	F	POS	16.98	24.86	POS	ASx												n/a
11	M	POS	33	26.48	POS	ASx												n/a
11	M	POS	29.63	20.77	POS	ASx												n/a
12	F	POS	17.77	23.91	POS	ASx												n/a
12	F	POS	19.38	21.69	POS	ASx												n/a
12	M	POS	28.13	24.42	POS	ASx												n/a
12	M	POS	26.13	21.45	POS	ASx												n/a
13	F	POS	21.41	26.51	POS	ASx												n/a
13	M	POS	15.02	23.09	POS	ASx												n/a
13	M	POS	18.81	22.28	POS	ASx												n/a
14	M	POS	23	23.72	POS	ASx												n/a
14	F	POS	34.35	25.54	POS	ASx												n/a
14	F	POS	25.82	24.55	POS	ASx												n/a
15	M	POS	23.74	20.75	POS	ASx												n/a
15	M	POS	32.1	22.45	POS	ASx												n/a
15	F	POS	21.48	22.93	POS	ASx												n/a
15	M	POS	24.18	22.59	POS	ASx												n/a
15	M	POS	16.09	23.35	POS	ASx												n/a
15	F	POS	21.04	23.6	POS	ASx												n/a
15	F	POS	20.9	23.6	POS	ASx												n/a
15	F	POS	30.4	25.71	POS	ASx												n/a
16	M	POS	16.99	21.01	POS	ASx												n/a
16	F	POS	18.29	23.6	POS	ASx												n/a
17	F	POS	19.81	21.22	POS	ASx												n/a
17	F	POS	18.1	22.44	POS	ASx												n/a
17	F	POS	17.2	24.71	POS	ASx												n/a
17	F	POS	24.45	24.72	POS	ASx												n/a
17	F	POS	21.3	26.47	POS	ASx												n/a
18	F	POS	35.73	23.96	POS	ASx												n/a
12	F	POS	27.2	22.72	NEG	Sx				Y		Y						0
12	F	POS	35.74	25.98	NEG	Sx			Y				Y		Y			1
14	F	POS	31.43	27.78	NEG	Sx	Y	Y	Y	Y	Y	Y	Y	Y	Y			4
15	F	POS	34.2	27.7	NEG	Sx	Y											1
1	M	POS	13.91	19.02	POS	Sx	Y							Y		Y		6
1	M	POS	15.21	25.39	POS	Sx	Y						Y	Y	Y			1
7	F	POS	26.84	26.63	POS	Sx		Y										2
9	M	POS	32.74	22.38	POS	Sx			Y	Y	Y		Y	Y			Y	1
9	F	POS	14.62	22.48	POS	Sx		Y		Y	Y		Y					2
10	F	POS	26.34	25.6	POS	Sx	Y									Y		2
10	F	POS	20.87	26.76	POS	Sx				Y				Y	Y	Y		1
11	M	POS	16.5	25.98	POS	Sx	Y	Y	Y	Y				Y	Y		Y	2
11	M	POS	27.67	20.53	POS	Sx	Y							Y				4
12	M	POS	26.22	26.25	POS	Sx	Y	Y	Y	Y			Y	Y	Y	Y		5
14	F	POS	12.21	23.05	POS	Sx	Y	Y	Y	Y	Y			Y	Y			3
14	F	POS	21.13	22.5	POS	Sx	Y	Y	Y	Y								2
14	F	POS	20.34	22.95	POS	Sx	Y		Y	Y			Y		Y			2
14	M	POS	17.74	23.27	POS	Sx	Y	Y	Y	Y			Y		Y	Y		7
16	F	POS	26.61	25.71	POS	Sx	Y	Y	Y	Y	Y		Y				Y	6
17	F	POS	21.69	26.48	POS	Sx		Y			Y			Y				4
17	F	POS	25.69	23.37	POS	Sx	Y	Y	Y			Y					Y	0
18	F	POS	24.75	27.03	POS	Sx	Y											1
18	M	POS	14.9	21.68	POS	Sx		Y		Y	Y							1
18	F	POS	30.63	22.9	POS	Sx	Y			Y			Y	Y	Y			1
18	F	POS	23.55	20.27	POS	Sx	Y		Y	Y		Y	Y	Y	Y		Y	4
18	M	POS	15.69	21.66	POS	Sx		Y		Y			Y	Y				1
2	F	POS	27.65	25.53	POS	Sx74		Y		Y				Y			Y	15
18	F	POS	26.79	27.71	POS	Sx74		Y		Y			Y	Y			Y	11

F, female; M, male; POS, positive; Ct, cycle threshold; N2, SARS-CoV-2 target; RP, host control target; ASx, asymptomatic; Sx, symptomatic; n/a, not applicable

Supplementary Table 3

Distribution of positive and negative BinaxNOW and RT-PCR results across clinical subgroups

Asymptomatic (Children: ≤18 yo)				Asymptomatic (Adults: >18 yo)			
BinaxNOW Ag	RT-PCR			BinaxNOW Ag	RT-PCR		
	Positive	Negative	Total		Positive	Negative	Total
Positive	70	7	77	Positive	40	4	44
Negative	37	715	752	Negative	17	913	930
Total (12.9% prevalence)	107	722	829	Total (5.9% prevalence)	57	917	974

Symptomatic ≤7 days (Children: ≤18 yo)				Symptomatic ≤7 days (Adults: >18 yo)			
BinaxNOW Ag	RT-PCR			BinaxNOW Ag	RT-PCR		
	Positive	Negative	Total		Positive	Negative	Total
Positive	22	0	22	Positive	82	0	82
Negative	4	65	69	Negative	3	270	273
Total (28.6% prevalence)	26	65	91	Total (23.9% prevalence)	85	270	355

Symptomatic (Children: >7 days)				Symptomatic (Adults: >7 days)			
BinaxNOW Ag	RT-PCR			BinaxNOW Ag	RT-PCR		
	Positive	Negative	Total		Positive	Negative	Total
Positive	2	0	2	Positive	10	1	11
Negative	0	6	6	Negative	5	35	40
Total (25% Prevalence)	2	6	8	Total (29.4% prevalence)	15	36	51

Supplementary Table 4

Predictive value of the Abbott BinaxNOW for detection of SARS-CoV-2 in samples from adult and pediatric (≤ 18) patients, with varying prevalence, based on observed sensitivity/specificity in each subgroup.

	Prevalence			
	20%	10%	5%	1%
PPV				
Adult, Sx ≤ 7 D	100%	100%	100%	100%
Adult, ASx	97.65% (93.91-99.12)	94.87% (87.27-98.03)	89.75% (76.45-95.93)	62.68% (38.39-81.91)
Pediatric, Sx ≤ 7 D	100%	100%	100%	100%
Pediatric, ASx	93.41% (88.32-96.38)	86.30% (77.06-92.20)	74.91% (61.41-84.85)	36.42% (23.40-51.80)
NPV				
Adult, Sx ≤ 7 D	99.17% (98.38-99.58)	99.63% (99.27-99.81)	99.82% (99.65-99.91)	99.97% (99.93-99.98)
Adult, ASx	93.15% (90.11-95.30)	96.83% (95.35-97.85)	98.47% (97.74-98.97)	99.70% (99.56-99.80)
Pediatric, Sx ≤ 7 D	96.30% (95.20-97.15)	98.32% (97.81-98.71)	99.20% (98.95-99.39)	99.84% (99.80-99.88)
Pediatric, ASx	91.89% (89.95-93.49)	96.23% (95.27-97.00)	98.18% (97.70-98.55)	99.64% (99.55-99.72)

PPV and NPV were calculated using the sensitivity and specificity observed in each subgroup for a hypothetical population of 1000 individuals per subgroup, with varying prevalence. PPV, positive predictive value; NPV, negative predictive value; Sx, symptomatic; ASx, asymptomatic; D, days

Supplementary Table 5

Performance of the Abbott BinaxNOW versus RT-PCR with varied Ct value cutoffs

	All Ct Values				Ct values ≤ 35				Ct values ≤ 30				Ct values ≤ 25			
	N	TP (+/+)	FN (+/-)	Sens	N	TP (+/+)	FN (+/-)	Sens	N	TP (+/+)	FN (+/-)	Sens	N	TP (+/+)	FN (+/-)	Sens
Combined All	292	226	66	77.4%	276	224	52	81.2%	214	205	9	95.8%	150	149	1	99.3%
All Children (Sx, ASx)	135	94	41	69.6%	125	92	33	73.6%	92	83	9	90.2%	62	61	1	98.4%
All Adult (Sx, ASx)	157	132	25	84.1%	151	132	19	87.4%	122	122	0	100.0%	88	88	0	100%
Sx ($\leq 7D$) Children	26	22	4	84.6%	25	22	3	88.0%	21	20	1	95.2%	14	14	0	100%
Sx ($\leq 7D$) Adult	85	82	3	96.5%	85	82	3	96.5%	76	76	0	100.0%	59	59	0	100%
ASx Children	107	70	37	65.4%	98	68	30	69.4%	69	61	8	88.4%	48	47	1	97.9%
ASx Adult	57	40	17	70.2%	51	40	11	78.4%	37	37	0	100.0%	24	24	0	100%

Ct, cycle threshold; TP, true positive (RT-PCR positive/BinaxNOW positive); FN, false negative (RT-PCR positive/BinaxNOW negative); Sens, sensitivity; Sx, symptomatic; ASx, asymptomatic; D, days; Ped, pediatric

Supplementary Table 6

Impact of temperature on BinaxNOW performance in individuals ≤ 7 days post symptom onset

BinaxNOW result	RT-PCR result					
	Temperature range: $\geq 59^{\circ}\text{F}$			Temperature range: 46-58.5 $^{\circ}\text{F}$		
	Positive	Negative	Total	Positive	Negative	Total
Positive	104	0	104	6	1	7
Negative	7	335	342	3	20	23
Total	111	335	446	9	21	30
Sensitivity	(104/111) 93.7%			(6/9) 66.7%		
Specificity	(335/335) 100.0%			(20/21) 95.2%		

The manufacturer recommends that tests be run at temperatures $\geq 59^{\circ}\text{F}$. Ag, antigen; Sx, symptoms

Supplementary Figure 1**Correlation of Cycle Threshold with BinaxNOW band strength**

Band strength (1= faint, n = 41; 2 = medium, n = 15; 3 = strong, n = 170) as interpreted by the first reader for the 226 true positive BinaxNOW tests correlated clearly with Ct value, with median Cts of 29.7 (27.6-32.7), 27.7 (25.5-29.1), and 19.5 (16.4-22.8), respectively.